OCT 5 2007

K070856

ICU MEDICAL INC.

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Salt Lake City, Utah
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Tracy S. Best, Sr. Regulatory Affairs Specialist

Preparation Date: March 23, 2007

510(K) Summary of Safety and Effectiveness for the:

Trade Name: ICU Medical Syringes, multiple sizes

Common Name: Syringe, Hypodermic

Classification Name: Piston Syringe, 21 CFR 880.5860, Class II Device

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Legally Marketed Predicate Devices for Substantial Equivalence:

*K024052 – Merit Medical Systems, Inc. (MMS)

Rationale for SE:

The MMS syringe is a Class II device pre-sterilized device that is intended for single use. Its components are: a calibrated hollow barrel and a moveable piston or plunger. At the end of the barrel, there is a tapered nozzle and a male luer hub. These are universal style connectors that are used for connecting a needle or connecting to other approved devices with a mating (female) luer connector. This predicate device, along with the submitted device operates similarly. The device works with a small amount of silicone oil that provides a lubricant for the moving piston shaft. The materials used in the submitted device and in the predicate devices are equivalent. The materials have previously been tested and accepted for biocompatibility and are widely accepted as medical industry grade material. Both the submitted device and the predicate are latex free.

Description of Submitted Device:

The ICU Medical Single-use Syringes is a pre-sterilized, single-use disposable that is equivalent to the predicate device. It is made of a calibrated hollow barrel, a moveable piston or plunger. Only two of the components ever touch the fluids or blood: the barrel and piston tip. All components are made from existing biocompatible materials that are routinely used in the medical device industry. This device works with a small amount of lubricant for moving the piston shaft. The connection luer on the end is identical to the predicate device. Syringe sizes include: 1ml; 3ml; 6ml; 10ml; 20ml; and 30ml. The barrel is visually clear, and the plungers are available in multiple colors (for indication of contents per hospital protocol).

Intended Uses of the ICU Medical Syringe:

ICU Medical piston syringes are single use syringes that are intended for injecting fluids into or withdrawing fluids from the body.

Technological Characteristics and Substantial Equivalence Table:

Component:	ICU Medical, Inc.	Merit Medical, Inc.
Syringe Barrel:	Polycarbonate	Polycarbonate
Plunger Tip:	Polyisoprene	Polyisoprene
Calibrated Barrel Volume:	YES	YES
Sterilization method:	EtO	EtO
510(k) Approval	This submission	K024052

The operational characteristics are identical in that by manually advancing or withdrawing the plunger in the barrel to express or withdraw fluids. Operation is the same for all piston syringes, including the predicate device.

Safety and Performance:

ICU Medical syringes will conform to the requirements of ISO 7886-1, an FDA recognized standard, prior to marketing the devices. Additionally, ICU Medical's Sterility Assurance Level, (SAL) has an established history of meeting the 10^{-6} level. The single use syringes will be packaged in a way as to ensure conformity with ISO 10993-1, including minimizing residual gases.

Conclusion:

The materials, performance, and operational features of both the submitted device and the predicate device are substantially equivalent and are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Tracy S. Best
Senior Regulatory Affairs Specialist
ICU Medical, Incorporated
4455 South Atherton Drive
Salt Lake City, Utah 84123

OCT 5 ˇ 2007

Re: K070856
Trade/Device Name: ICU Medical Sterile Disposable Piston Syringes, Sizes: 1ml; 3ml; 6ml; 10ml; 20ml; & 30ml
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: September 24, 2007
Received: September 25, 2007

Dear Mr. Best:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

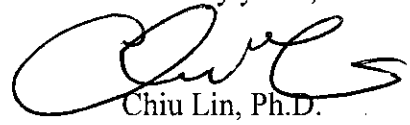
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

ICU Medical sterile disposable piston syringes, Sizes: 1ml; 3ml; 6ml; 10ml; 20ml; & 30ml

Indications for Use:

ICU Medical piston syringes are single use syringes that are intended for injecting fluids into or withdrawing fluids from the body.

Prescription Use __XX__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K970356